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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,265	04/04/2005	Richard Andrew Snell	04150.0017U1	8824
23859 7590 12/10/2007 NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			EXAMINER HALL, DEANNA K	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 12/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,265	Applicant(s) SNELL ET AL.	
	Examiner Deanna K. Hall	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-18 is/are rejected.
- 7) ☒ Claim(s) 2-4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on January 25, 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>April 4, 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgments

1. This second non-final office action is in response to the reply filed on September 17, 2007.
2. In the reply, the applicant resubmitted a copy of FR 2,292,487 which is being considered.
3. Claims 1-18 remain pending in the application.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on April 4, 2005 is in compliance with the provisions of 37 CFR 1.97(b). Accordingly, the IDS is being considered by the Examiner.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1, 5, 7-9, 11, 14-15 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Haber et al. (US 5,445,614) ("614").** The '614 patent discloses: a two-part syringe S comprising two chambers 14, 24 each with an associated plunger P₁, P₂ interlinked so as selectively to prevent movement of one of said plungers in its respective chamber dependent upon the position of the other plunger C3 L6-13. The interlinking of the '614 patent is configured to be capable of reconstituting and injecting a lyophilized drug C1 L55- C2 L2. The two chambers of the '614 patent can be placed selectively in fluid communication with one another C3 L24-27. The '614 patent further discloses a communicating conduit 66 and a seal associated with one or both of the chambers C2 L60-62. The '614 patent discloses a tortuous or complex fluid path, Fig. 3. The fluid connection of the '614 patent is selectively engageable with the two chambers by means of valve 30. The conduit 66 is provided on a support member 60 separate from the two chambers, see Fig. 2.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haber '614 in view of Haber et al. (US 5,147,323) ("323").

The '614 Haber patent discloses the invention as substantially claimed (see above). However, the '614 patent does not directly disclose the communicating conduit comprising one or two needles for breaching the seal. The Haber '323 patent, in the analogous art, teaches a communicating conduit 50 comprising one or two needles 52, 53 for breaching said seals (36), C3 L42-47. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of the '614 patent with the needles for breaching the seals as taught by the '323 patent for mixing the components of the individual chambers.

9. Claims 12-13, 16 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haber '614 in view of Pizzino (US 4,610,666).

The '614 Haber patent discloses the invention as substantially claimed (see above). However, the '614 patent does not directly disclose the communicating conduit being provided on a separate plastic support member which is slidable towards or away from the chambers. Pizzino, in the analogous art, teaches a separate slidable support member 40. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the device of the '614 patent with the slidable support member as taught by Pizzino for selective engagement with the chambers. Pizzino further teaches plungers having a different appearance C3 L62- C4 L27 in accordance with claim 6.

Allowable Subject Matter

10. Claims 2-4 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: The primary reason for indication of allowability of the subject matter of claims 2-4 is the limitation of the cam track associated with the plungers and the perpendicular cam shuttle member comprising followers for each cam track. These limitations are not disclosed, nor thought in the prior art of record.

Response to Arguments

11. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deanna K. Hall whose telephone number is 571-272-2819. The examiner can normally be reached on M-F 9:00am-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deanna K. Hall
Examiner
AU 3767

dkh

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

